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EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/864,921	REED ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *16 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 31-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 31-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's amendment is acknowledged.

Priority

2. Applicant's correction of the priority information is acknowledged.

Claim Objections

3. The objection to Claim 6 is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-8 and 31-38 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The current claims are drawn to a isolated nucleic molecules encoding polypeptides comprising SEQ ID NO: 97 and DNA which hybridizes to these seuqecnes.

Credible Utility

Following the requirements of the Utility Guidelines (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for Utility.), the first inquiry is whether a credible utility is cited in the specification for use of the nucleic acid molecule which encodes SEQ ID NO: 97. The only cited utilities identified by the examiner is a reach through utility to use the Clan-A (SEQ ID NO: 97)(see paragraph

0028) where Clan-A is used in interactions with other Card proteins in ways that "likely influence apoptosis, cytokine processing, or NF-kB activity (see paragraph 0043 of the specification)." These utilities are credible.

Upon identification of credible utilities, the next issue is whether there are any well established utilities for the nucleic acid molecule which encodes SEQ ID NO: 97, including 15-mer fragments of SEQ ID NO: 97. No well established utilities for this nucleic acid molecule which encodes SEQ ID NO: 97 are identified in either the specification or in the cited prior art.

Substantial utility

Given the absence of a well established utility, the next issue is whether substantial utilities are disclosed in the specification. Here, there is no evidence of any substantial utility. No particular use for SEQ ID NO: 97 is found in the specification nor is there any use for any method involving SEQ ID NO: 97.

As noted in the utility guidelines, methods of treating unspecified diseases, basic research on a product to identify properties, intermediate products which themselves lack substantial utility are all insubstantial utilities (see page 6 of the Utility guideline training materials). If there were evidence of the association of SEQ ID NO: 97 with any disease state or with some other biological phenotype, this evidence might be considered regarding a substantial utility. However, no such evidence is found. In fact, the specification indicates that the Clan molecules can have opposing functions, so that some Clan molecules may trigger pro-caspase-1 activation while others may inhibit this activation. Further, even if the phenotype is pro-caspase-1 activation, this phenotype

does not meet the requirements for a "substantial" utility since the specification provides no information on how to use such a phenotype.

Applicant's own paper supports a conclusion that there is no "real world" use, other than further investigation, for SEQ ID NO: 97. In Damiano et al (Genomics (2001) 75:77-83), Damiano states "Once their physiologic functions are uncovered, CLAN proteins may prove to be valuable therapeutic targets (see abstract)." So even Applicant, at a time later than that of the submission of this application, indicates that the physiologic functions of CLAN proteins are unknown, and they "may" be valuable targets. Of course, depending upon the physiologic function, any protein "may" be a valuable target. It is the requirement of the 35 U.S.C. 101 that the invention submitted have utility when filed, not at some indefinite time in the future when further experimentation has reached its successful conclusion.

The cited utilities of pro-caspase-1 activation or inhibition have less "real world" significance than the amount of utility found insufficient by the Supreme court in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966). In Brenner, a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an

invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that:

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. . . . a patent is not a hunting license. . . .[i]t is not a reward for the search, but compensation for its successful conclusion.

The instant claims are drawn to polynucleotides encoding a protein (SEQ ID NO: 97) which has no identified cellular role, no particular cellular phenotype and is not associated with any disease. The function of the Clan-A (SEQ ID NO: 97) gene and its resulting protein are as yet undetermined with no known function or biological significance. Until some actual and specific significance can be attributed to the protein identified in the specification, or the gene encoding it, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. Thus, there is no immediately apparent or "real world" utility as of the filing date directly consistent with *Brenner v. Manson*. Therefore, it is concluded that the claims lack substantial utility.

Specific Utility

In the current case, there is no specific utility for SEQ ID NO: 97 or methods using this sequence. No specific association of SEQ ID NO: 97 and any disease or even a specific biological phenotype is provided in the specification. The specification discusses a wide variety of phenotypes which might be influenced by Clan-A, SEQ ID NO: 97, such as cytokine processing, NF-KB activity or apoptosis (see paragraph

0043), but does not specifically teach any use for the sequence in association with these multiple generic possiblities. Even the claims are drawn to generic utilities as shown by nonelected claim 23, where the biological process includes elements ranging from apoptosis to inflammation, cell adhesion and, most generic of all, transcription. Potentially any fragment of nucleic acid is of commercial importance to someone, but this is not specific in any way to SEQ ID NO: 97.

Finally, with regard to the utility analysis, the current situation directly tracks Example 9 of the utility guidelines, where a nucleic acid of significantly unknown function was characterized as lacking utility.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-8 and 31-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Nature of Invention

Claims 1-8 are drawn to a system and method of screening using SEQ ID NO: 97. The nature of this invention relates to nucleic acids of a particular sequence with no

other associated information. This is an invention in a subject area which is well recognized as unpredictable.

Breadth of the claims

The claims are drawn to a oligonucleotides which encode SEQ ID NO: 97, to fragments as small as 15 nucleotides from oligonucleotides which encode SEQ ID NO: 97 and to any sequence which will hybridize to an oligonucleotide which encodes SEQ ID NO: 97 under moderately stringent conditions.

Amount of Guidance in the Specification

The specification discloses the entire sequence of the SEQ ID NO: 97 and discloses one particular DNA sequence which encodes SEQ ID NO: 97, but identifies no particular use for the sequence. As noted in the utility rejection above, this utility is not found to be substantial nor specific and consequently, the specification provides NO guidance regarding how to use the oligonucleotide encoding SEQ ID NO: 97 or the broader embodiments of fragments and hybridizing oligonucleotides.

In fact, the specification indicates that "different isoforms of CLAN likely have opposing effects on pro-caspase-1 activation (see paragraph 0043)." Thus, the specification indicates that one cannot predict the function or use of the molecule based upon the sequence whatsoever. The specification here is admitting that even very closely related molecules may differ significantly in function.

Working Examples

There are NO working examples in which an oligonucleotide encoding SEQ ID NO: 97 is used in any assay for detection or diagnosis of any disease or any other related utility.

Amount of Guidance in Prior Art

As noted in the utility rejection above, the prior art provides no guidance with regard to the particular function of SEQ ID NO: 97. In fact, Applicant's own paper supports a conclusion that there is no "real world" use, other than further investigation, for SEQ ID NO: 97. In Damiano et al (Genomics (2001) 75:77-83), Damiano states "Once their physiologic functions are uncovered, CLAN proteins may prove to be valuable therapeutic targets (see abstract)." So even Applicant, at a time later than that of the submission of this application, indicates that the physiologic functions of CLAN proteins are unknown, and they "may" be valuable targets. Of course, depending upon the physiologic function, any protein "may" be a valuable target. Damiano further notes "The physiological functions of the isoforms of CLAN remain to be delineated (see page 83, column 1)." It is the requirement of the 35 U.S.C. 112, first paragraph that the invention submitted have utility and be enabled when filed, not at some indefinite time in the future when further experimentation has reached its successful conclusion.

Skill in the Art

While no evidence is adduced, the examiner believes the skill in the art would be considered high.

Predictability of the Art

The art in biotechnology, as relates to the association of diseases with particular genes, is highly unpredictable. The claimed sequence is currently an orphan gene. Regarding such Orphan genes, Dujon (Trends in Genetics (1996) 12(7):263-270) notes that the most striking result of yeast sequencing is that "a significant proportion of yeast

genes are orphans of unpredictable function (abstract)". Dujon further states "We have no clue to which direction to search and, even worse, when considering the experiments that could be done on orphans, we rapidly find ourselves intellectually embedded in the schemes of the past (page 2169, column 2)." Thus, it is extremely unpredictable what to do with an orphan gene such as SEQ ID NO: 97 in the absence of any defined utility.

Further, there is an abundance of evidence that very similar proteins can perform very different functions. For example, Rost et al (J. Mol. Biol. (2002) 318(2):595-608) notes regarding assignment of enzymatic activity based upon homology comparisons that "The results illustrated how difficult it is to assess the conservation of protein function and to guarantee error-free genome annotations, in general: sets with millions of pair comparisons might not suffice to arrive at statistically significant conclusions (abstract)." Thus, even high levels of homology do not necessarily correlate with actual protein function.

So the prior art supports a finding that it is entirely unpredictable what use can be made of SEQ ID NO: 97 in the absence of any teaching in the specification.

Quantity of Experimentation

An immense amount of experimentation would be required in order to define whether this protein is associated with any particular disease state. In order to acquire statistically significant evidence of an association with a disease or other utility, dozens of patients in each of the many hundreds of different possible disease states would need to be subjected to collection of samples for analysis of their DNA, followed by analysis and the inventive efforts of determining if any association exists. This is a very large quantity of experimentation.

Determination

In view of the unpredictable nature of the invention, the absence of any guidance in the specification for a substantial and specific use, the absence of any working examples in the specification, the negative teachings in the prior art, the extreme unpredictability of the invention, and the large amount of experimentation necessary balanced against the high level of skill in the art and the relatively narrow breadth of the claims, it is concluded that undue experimentation would be required to use this invention as claimed.

Claim Rejections - 35 USC § 112 – Written Description

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 31 and 33-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number'' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed

by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

All of the current claims encompass a genus of nucleic acids which are different from those disclosed in the specification, since the claims are not limited to any particular SEQ ID NO, but are open to a nucleic acid which hybridizes to a nucleic acid that encodes SEQ ID NO: 97 or which comprise 15 nucleotides of a particular Sequence. (With regard to claim 2, in view of the broadening effect of claim 6, this claim is included in the rejection since it may encompass fragments, as per the dependent claim). Most significantly, the genus includes variants for which no written description is provided in the specification. This large genus is represented in the specification by only the particularly named SEQ ID No 97. Thus, applicant has express possession of only one particular sequence in a genus which comprises hundreds of millions of different possibilities. Here, no common element or attributes of the sequences are disclosed, not even the presence of certain domains.

There is no showing or evidence which links structural limitations or requirements to any particular functional limitations. Further, these claims encompass alternately spliced versions of the proteins, allelic variants including insertions and mutations, inactive precursor proteins which have a removable amino terminal end, and only specific nucleic and amino acid sequences have been provided. No written description of alleles, of upstream or downstream regions containing additional sequence, or of alternative splice variants has been provided in the specification.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

> "A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition of the nucleic acids as encoding an Clan-A protein lacks any specific structure, since it is in the absence of knowledge of the material composition.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

The current situation is a definition of the compound without identifying the structure function relationship of the compound, so that the compound is claimed solely as a

nucleic acid which hybridizes to a nucleic acid which encodes an SEQ ID NO: 97 without any additional functional limitations and without any definite structure.

In the instant application, SEQ ID NO: 97 is described. However, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed which comprise SEQ ID NO 97. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 6, 31 and 33-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al (Genbank Locus AQ309404 (Dec. 22, 1998)).

Adams teaches an isolated nucleic acid molecule encoding a DNA that would hybridize to a nucleic acid encoding SEQ ID NO: 97 under highly stringent conditions as required by claims 31 and 33.

With regard to claim 34, Adams teaches the vector pBELOBAC11.

With regard to claim 35, Adams teaches the availability of clones.

With regard to claims 6 and 36, Adams teaches an isolated oligonucleotide which comprises more than 15 nucleotides, and in fact, at least 552 contiguous nucleotides of the nucleic acid molecule of claim 2.

With regard to claim 37, Adams teaches that the sequence is in a Bac vector, which comprises DNA, which is a detectable marker.

With regard to claim 38, Adams teaches that the clones are available from Research Genetics.

Response to Arguments

12. Applicant's arguments filed July 16, 2004 have been fully considered but they are not persuasive.

Utility

Applicant repeatedly argues that the utility of CLAN-A is that it can trigger pro-caspase-1 activation by the "induced proximity" mechanism and cites page 16 of the specification. However, THIS IS NOT TRUE. The argument does not correctly describe the teaching of the specification. The Applicant never identifies support in the specification for the statement that CLAN-A can trigger pro-caspase-1 activation, but rather makes the generic statement that "Another characteristic of the invention CARD-containing polypeptides is that they can associate with pro-caspases, caspases or with caspase-associated proteins, thereby altering caspase proteolytic activity. (see page 16, lines 14-18)." So contrary to Applicant's argument that some sort of specific use is

contemplated for CLAN-A at page 16, no such use is cited. Rather, the specification generically discloses a function imputed to CARD domains, but with absolutely no evidence that CLAN-A has this function. In fact, the specification itself disputes this utility, noting that "different isoforms of CLAN likely have opposing effects on pro-caspase-1 activation (see paragraph 0043)." So there is no expectation whatsoever that CLAN-A will necessarily function to trigger caspase activation, even based upon the teachings of the specification itself.

Applicant then cites a series of generic utilities, relevant to any nucleic acid whatsoever, to support utility for CLAN-A. Each of these utilities lacks any specific or substantial utility apart from the protein encoded by the nucleic acid itself. That is, without any direct knowledge of a use of the protein, there is no specific or substantial use for the nucleic acids which are being claimed.

Applicant then attempts to distinguish Brenner v.Manson. In considering the issues presented in this response, special attention must be paid to the Brenner court's statement that a patent should issue only when an invention possesses "substantial utility," i.e., "where a specific benefit exists in currently available form." Whether a claimed invention is useful under 35 U.S.C. § 101 is a question of fact. Cross v. Iizuka, 753 F.2d 1040, 1044 n.7, 224 USPQ 739, 742 n.7 (Fed. Cir. 1985). The Court concluded that "[t]he basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient

justification for permitting an applicant to engross what may prove to be a broad field." Id. at 534-35, 148 USPQ at 695.

Applicant then disparages Brenner by arguing that the utility in that case was not stated in the specification. However, In re Kirk, 376 F.2d 936, 153 USPQ 48 (CCPA 1967) discussed a situation of steroid derivatives mentioned in the specification. The invention claimed in Kirk was a set of steroid derivatives said to have valuable biological properties and to be of value "in the furtherance of steroidal research and in the application of steroidal materials to veterinary or medical practice." Id. at 938, 153 USPQ at 50. The claims had been rejected for lack of utility. In response, the applicants submitted an affidavit which purportedly "show[ed] that one skilled in the art would be able to determine the biological uses of the claimed compounds by routine tests." Id. at 939, 153 USPQ at 51.

The court held that "nebulous expressions [like] 'biological activity' or 'biological properties'" did not adequately convey how to use the claimed compounds. Id. at 941, 153 USPQ at 52. Nor did the applicants' affidavit help their case: "the sum and substance of the affidavit appear[ed] to be that one of ordinary skill in the art would know 'how to use' the compounds to find out in the first instance whether the compounds are—or are not—in fact useful or possess useful properties, and to ascertain what those properties are." Id. at 942, 153 USPQ at 53.

The Kirk court held that an earlier CCPA decision, holding that a chemical compound meets the requirements of § 101 if it is useful to chemists doing research on steroids, had effectively been overruled by Brenner. "There can be no doubt that the

insubstantial, superficial nature of vague, general disclosures or arguments of 'useful in research' or 'useful as building blocks of value to the researcher' was recognized, and clearly rejected, by the Supreme Court" in Brenner. See Kirk, 376 F.2d at 945, 153 USPQ at 55.

So when the Kirk court was faced with a situation in which the compound was identified as a steroid in the specification, that identification alone was insufficient to impart utility, when the specific use of the steroid was not known.

Further, as noted in the rejection, there is no specific use for the nucleic acids. An invention certainly can have a utility that is shared by other compounds or compositions. Take, for example, an application that claims ibuprofen and discloses that it is useful as an analgesic. No one would argue that a claim to ibuprofen lacks utility simply because aspirin and acetaminophen are also useful as analgesics. On the other hand, not every utility will satisfy § 101, even if the utility is shared by a class of inventions. Assume that the above-described application did not disclose that ibuprofen was an analgesic but only disclosed that it is useful because it can be used to fill a jar, which would then be useful as a paperweight. There would be little doubt that this disclosed utility would not satisfy § 101, even though the utility is shared by a large class of inventions, viz., those whose physical embodiments have mass. So while a utility need not be unique to a claimed invention, it must nonetheless be specific, and in currently available form, in order to satisfy § 101.

In the current case, there is no specific utility for the nucleic acid claimed. It is only functional as a subject of further research. Applicant can point to no specific use

for the nucleic acid where it can be used in a substantive way in currently available form.

Enablement

Applicant then argues the enablement rejection. While many of the same arguments discussed above apply to the enablement rejection, Applicant makes some further statements which are not found persuasive.

Applicant argues that it is irrelevant that Damiano teaches that the functions of the CLAN proteins was unknown at a time post filing and that no particular use was disclosed for these proteins. This is incorrect. It is significant that even after the filing date of the current application, the art (and in particular the applicant), had no idea of how to use the claimed molecules.

When Applicant argues that implicitly a therapeutic use for the nucleic acids is being required, that is simply not true. What is required is a use, and no such use is provided. If Applicant could show that, for example, that the CLAN-A nucleic acid was diagnostic of something, expressed a protein that itself had utility, or show any specific and substantial utility whatsoever, that would be adequate. However, no such utility is provided.

Applicant does not significantly rebut any of the determinations made with regard to the Wands factors. When Applicant concludes that there must be a patentable utiilty enabled by the specification, that is correct, but no such utility is present in the specification and there is no such utility cited. Therefore, the conclusion that the claims lack enablement is maintained.

Description

Applicant then argues the description rejection. While Applicant is correct that the rejection no longer applies to claims 1-8, the rejection remains applicable to newly filed claims for the reasons given in the rejection and is therefore applied to claims 31 and 33-38.

Anticipation

Applicant then argues the anticipation rejection. As with description, the rejection no longer applies to claims 1-5, 7 and 8, but the rejection remains applicable to claim 6 and to new claims 31 and 33-38 for the reasons given in the rejection. Applicant does not appear to separately argue the fragment claims.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman
Primary Examiner
Art Unit 1637
8/31/04